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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,178	12/01/2003	Dennis O'Brien	S63.2-13172-US01	2053

490 7590 04/03/2007  
VIDAS, ARRETT & STEINKRAUS, P.A.  
6109 BLUE CIRCLE DRIVE  
SUITE 2000  
MINNETONKA, MN 55343-9185

EXAMINER
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YABUT, DIANE D

ART UNIT	PAPER NUMBER
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3734

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/03/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/725,178

Applicant(s)

O'BRIEN ET AL.

Examiner

Diane Yabut

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 December 2003.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-24 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 16 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 4/14/04; 3/25/04  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Information Disclosure Statement*

1. The information disclosure statements (IDS) submitted on 14 April 2004 and 25 March 2004 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

### *Claim Objections*

2. Claims 2-14, 16-19, and 21-24 are objected to because of the following informalities: On line 1 of the claims it reads "A cutting balloon" and should be changed to --The cutting balloon--. Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 8, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by **Barath** (U.S. Patent No. **5,616,149**).

Claim 1: Barath discloses an elongated balloon 2 defining a longitudinal axis, said balloon being inflatable from a first deflated configuration to a second radially expanded

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configuration, and an elongated incising element **6** mounted on said balloon and oriented longitudinally, said incising element having a length and extending radially from said balloon to an operative surface feature capable of incising tissue, and a radially compressible sheath **17** mounted on said balloon along the length of said incising element and extending radially from said balloon and beyond said surface feature when said balloon when said balloon is in the first configuration to protect said surface feature during transit to the treatment site, said sheath being positioned for radial compression between said tissue and said balloon to expose said surface feature for tissue incision when said balloon is inflated into the second configuration (Figures 11-13; col. 5, lines 14-36).

Claim 2: Barath discloses a mounting pad **13** for attaching said incising element to said balloon (col. 5, lines 14-19).

Claim 8: Barath discloses said incising element **6** being a blade and said surface feature is a cutting edge (col. 5, lines 14-36).

Claim 10: Barath discloses said cutting edge of said blade **6** being embedded in said sheath **17** when said balloon **2** is initially in said first configuration, said cutting edge oriented relative to said balloon to cut through said sheath for exposure of said cutting edge to incise tissue during radial compression of said sheath (Figures 11-13; col. 5, lines 14-36).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Barath** (U.S. Patent No. **5,616,149**).

Claims 11-14: Barath discloses the claimed device except for the incising element being a round wire or made of a hardened polymer, and the sheath being made of a low durometer material or a porous polyurethane material. It would have been obvious to one of ordinary skill in the art at the time of invention to provide these materials to the incising element and sheath of Barath, since it was known in the art that these are beneficial as biocompatible materials that facilitate the cutting mechanisms in angioplasty procedures.

7. Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Barath** (U.S. Patent No. **5,616,149**), as applied to Claim 2 above, and further in view of **Vigil** (U.S. Patent No. **5,320,634**).

Claim 3: Barath discloses the claimed device except for the incising element being partially encapsulated in said mounting pad and said mounting pad is bonded to said balloon.

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Vigil teaches an incising element **31** being partially encapsulated in said mounting pad **32** and said mounting pad is bonded to said balloon **18** (Figure 3A; col. 4, lines 17-34). It would have been obvious to one of ordinary skill in the art at the time of invention to provide the incising elements as partially encapsulated in said mounting pad, as taught by Vigil, to Barath in order keep the incising element covered or protected and more securely mounted to prevent detachment from balloon.

Claim 4: Barath discloses the sheath **17** being attached to said mounting pad **13** (Figures 12-13).

8. Claims 5-7, 15-16, 18-22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Barath** (U.S. Patent No. **5,616,149**), as applied to Claim 1 above, and further in view of **Shiber** (U.S. Patent No. **6,730,105**).

Claims 5-6, 15, 20, and 22: Barath discloses the claimed device (see above discussion for Claims 1, 2, and 8 above), except for the sheath having a pair of sheath members with each sheath member being shaped as a hollow, elongated tube and positioned or mounted longitudinally on said balloon to interpose said blade between sheath members, each said sheath member made of a flexible material to radially compress between said tissue and said balloon to expose a preselected portion or said cutting edge of said cutting blade for tissue incision during an inflation of said balloon.

Shiber teaches a sheath (upper surface of element **15**) having a pair of sheath members (on either side of cutting blade **54**) with each sheath member being shaped as a hollow, elongated tube and positioned or mounted longitudinally on said balloon to

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interpose said blade between sheath members, each said sheath member made of a flexible material to radially compress between said tissue and said balloon to expose a preselected portion or said cutting edge of said cutting blade for tissue incision during an inflation of said balloon (Figure 18; col. 6, lines 8-21). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a pair of sheath members between the cutting blade, as taught by Shiber, to Barath in order to reduce the likelihood of the balloon or tissue being damaged by the cutting edge during introduction and advancement or withdrawal of the catheter in the vasculature.

Claims 7, 18-19, and 24: Barath discloses the claimed device except for each said sheath member extending a radial distance,  $d$ , from said balloon when uncompressed and said incising element extends a distance,  $D$ , from said balloon, with  $d > D$  and being substantially rectangular shaped in a plane normal to said direction of tube elongation.

Shiber teaches each said sheath member (upper surface of element **15**) extending a radial distance,  $d$ , from said balloon **15** when uncompressed and said incising element **54** extends a distance,  $D$ , from said balloon, with  $d > D$  (Figure 18; col. 6, lines 8-21). It would have been obvious to one of ordinary skill in the art at the time of invention to provide said sheath members extending a radial distance that is greater than the distance the incising element extends from the balloon, as taught by Shiber, to Barath in order to reduce the likelihood of the balloon or tissue being damaged by the cutting edge during introduction and advancement or withdrawal of the catheter in the vasculature. Although Shiber does not necessarily teach substantially rectangular shaped sheath members, it does have a shape extending in a plane normal to said

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direction of tube elongation, and it appears that they would function the same as rectangularly shaped sheath members in protecting the cutting element.

Claim 16: Barath discloses a mounting pad **13** for attaching said incising element to said balloon (col. 5, lines 14-19).

Claim 21: Barath discloses the claimed device except for the blade having a first side and a second side and each said sheath member is in contact with a portion of respective side to define said pre-selected exposed portion of said cutting blade.

Shiber teaches the blade **54** having a first side and a second side and each said sheath member is in contact with a portion of respective side (with element **53**) to define said pre-selected exposed portion of said cutting blade (Figure 18; col. 6, lines 8-21). ). It would have been obvious to one of ordinary skill in the art at the time of invention to provide the sheath member in contact with first and second sides of the blade, as taught by Shiber, to Barath in order to reduce the likelihood of the balloon or tissue being damaged by the cutting edge during introduction and advancement or withdrawal of the catheter in the vasculature.

9. Claims 9 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Barath** (U.S. Patent No. **5,616,149**) and **Shiber** (U.S. Patent No. **6,730,105**), as applied to Claims 8, 16, and 21 above, and further in view of **Vigil** (U.S. Patent No. **5,320,634**).

Claims 9, 17, and 23: Barath and Shiber disclose the claimed device, including Shiber teaching each said sheath member (upper surface of element **15**) having an azimuthal width  $w$ , and wherein said blade **54** has an azimuthal width,  $W$ , where said



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blade extends from said mounting pad, with  $w > 2W$  (Figure 18; col. 6, lines 8-21). It would have been obvious to one of ordinary skill in the art at the time of invention to provide said sheath members having greater than 2 times the azimuthal width of said blade, as taught by Shiber, to Barath in order to reduce the likelihood of the balloon or tissue being damaged by the cutting edge during introduction and advancement or withdrawal of the catheter in the vasculature. Barath and Shiber disclose the claimed device except for said blade being partially encapsulated in a mounting pad that is bonded to said balloon (see discussion for Claim 3 above).

Vigil teaches an incising element **31** being partially encapsulated in said mounting pad **32** and said mounting pad is bonded to said balloon **18** (Figure 3A; col. 4, lines 17-34). It would have been obvious to one of ordinary skill in the art at the time of invention to provide the incising elements as partially encapsulated in said mounting pad, as taught by Vigil, to Barath and Shiber in order keep the incising element covered or protected and more securely mounted to prevent detachment from balloon.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY

A handwritten signature in black ink, appearing to read "M J Hayes", with a long horizontal flourish extending to the right.

MICHAEL J. HAYES  
SUPERVISORY PATENT EXAMINER